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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,182

Applicant(s)

STAHLER ET AL.

Examiner

Dwayne K. Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 33, 36-39, 45, 46 and 49-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Zanzucchi et al. (WO 96/15450). Zanzucchi teaches a microfluidic device for processing and analyzing multiple samples in wells. The device is comprised of a disc (14) having a flow channel structure that includes series of reaction areas (34, 36, 40, 42, 44) connected to feed channels (34, 50) and drain channel (46). The loading channel (50) feeds fluids in a vertical manner that is perpendicular to the flow channel structure. Loading channel (34) is a horizontal channel that flows parallel to flow channel structure. Figures 11A and 11B show other embodiments having vertical channels that provide feed and drain channels (315) that are perpendicular to the reaction areas. This embodiment also shows flow channel structures that are on both sides of the reaction support (instant claim 7). The use of glass for the disc (14) is taught on page 8, lines 1-11. A cover sheet of glass is disclosed at page 11, line 18.

Figures 7C and 8 show a valve system that uses gating electrodes (162) for controlling fluid flow in the reactors and reservoirs. The valve system is described on page 16, lines 19-34. Zanzucchi teaches DNA binding and synthesis on page 11 and shows array synthesis on page 17.

3. Claims 33, 36-39, 45, 46 and 49-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfof et al. (6,485,690). Pfof teaches a multilayered fluidic array having microchannels, reservoirs and reaction wells. The device is best shown in Figures 1, 2 and 6-8. This embodiment is described at column 5, line 50 – column 6, line 46. The device is comprised of several layers (12, 14 and 16) having flow channels that run parallel (26) to the layers as well as flow channels that are perpendicular (20, 22, 32, 34) to the layers. Flow channel 20 is a feed channel, while channel 34 serves as a drain. The bottom layer of the device contains reaction wells (30). Pfof discloses materials of construction including glass and silicon in column 6, lines 33-40. DNA synthesis and receptor binding is taught in column 5, lines 1-48.

Inventorship

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (WO 96/15450) in view of Kellogg et al. (6,143,248). Zanzucchi teaches every element of claims 34 and 35 except for channels having tapered or non-uniform cross sections. Kellogg teaches a microfluidic device. The channels in the device may contain tapering or non-uniform sections for passively controlling fluid flow in the device (Figures 2A, 2B and 10. See columns 18 and 29). It would have been

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obvious to combine the non-uniform channels from Kellogg with the device of Zanzucchi. One would add the channel structures from Kellogg in order to provide passive control of fluids flowing in the device.

7. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfof et al. (6,485,690) in view of Craighead (5,867,266). Pfof teaches every element of claim 8 except for microlens structures integrated specifically into the cover layer. Pfof does state that microlenses may be integrated any layer of their device (column 11, lines 40-55). Craighead teaches an optical analysis device having multiple channels (12, 14, 16, 18) for containing DNA samples to be analyzed. The channels are aligned with microlenses (32, 34, 36, 38) that focus laser beams to the channels such that labeled DNA fragments will fluoresce at a known wavelength (column 5, lines 1-29). It would have been obvious to one of ordinary skill in the art to add the microlenses from Craighead to the cover layer of Pfof. One would add the microlenses to the cover layer in order to focus and direct light in the device.

8. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (WO 96/15450) in view of Paffhausen et al. (6,191,852). Zanzucchi teaches every element of claim 41 except for the parallel fused glass fibers. Paffhausen teaches a measurement system for detecting optical signals from the surface of a planar object. The device includes a bundle of fused fiber optics. It would have been obvious to one of ordinary skill in the art to combine the fiber optic bundle of Paffhausen

with the device of Zanzucchi. In column 5, lines 12-54 Paffhausen teaches that the fiber optic bundle allows for an increase in the sensitivity of the system for the transmission of optical signals. One would add the fiber optic bundle in order to take advantage of this increased sensitivity.

9. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (WO 96/15450) in view of Parce et al. (WO 98/02728). Zanzucchi teaches every element of claim 10 except for making walls lightproof. Parce teaches a microfluidic system for electrophoretic analysis of materials. The device is comprised of substrates having microchannels. An embodiment of the device disclosed on page 14 (line 34) includes a mask imposed on the substrate to provide darkened regions that shield areas of the channels from light during optical analysis. It would have been obvious to one of ordinary skill in the art to combine the mask element from Parce with the device of Zanzucchi. One would add the mask to selectively darken elements of the device and prevent interference from reflected light.

10. Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi et al. (WO 96/15450) in view of Siegmund (3,979,637). Zanzucchi teaches every element of claims 43 and 44 except for the use of glass fiber bundles for the channels. Siegmund teaches microchannel plates comprised of large numbers of glass fibers bundled together. The glass prevents cross talk of electrical energy between the channels (Abstract). It would have been obvious to one of ordinary skill in

the art to combine the glass channels from Siegmund with the device of Zanzucchi. One would use the glass channels in order to prevent electrical cross talk between channels as suggested by Siegmund.

11. Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfof et al. (6,485,690) in view of Stabile et al. (5,872,623). Pfof teaches every element of claim 16 except for a CCD integrated into cover layer. Pfof does state that optical or detection elements may be integrated any layer of their device (column 11, lines 40-55). Stabile teaches an apparatus for detecting light from closely spaced detection sites. The embodiment most relevant to the instant claims is shown in Figure 6 and described in column 11, lines 30-46. In Figure 6, Stabile shows 3 layers with the lower layer having a CCD. It would have been obvious to one of ordinary skill in the art to add the CCD layer from Stabile to the device of Pfof. One would add the CCD to detect light emitted from the analyzed material in the wells.

Response to Arguments

12. Applicant has argued that both Zanzucchi and Pfof fail to teach channels with non-uniform cross sections as "claimed by claim 33". The Examiner notes, however, that these features are recited in claims 34 and 35 – not claim 33. In addition, the Examiner has provided a new rejection that includes the reference "Kellogg" to address these features.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DKH

December 11, 2006


Jill Warden
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